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510(k) SUMMARY

OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM

November 5, 2012

1 General Information

- Applicant:

OLYMPUS MEDICAL SYSTEMS CORP.
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Establishment Registration No.: 8010047

- Official Correspondent:

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- Manufacturer:

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OLYMPUS MEDICAL SYSTEMS CORP.
HINODE PLANT
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190-0182, Japan
Establishment Registration Number: 3003637092

2 Device Identification

- Device Trade Name: OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM
- Common Name: Capsule Imaging System
- Regulation Number: 21 CFR 876.1300
- Regulation Name: Ingestible telemetric gastrointestinal capsule imaging system

- Regulatory Class: II (Special Controls)
- Classification Panel: Gastroenterology/Urology
- Product Code: NEZ

3 Legally Marketed Device to which Substantial Equivalence is Claimed

The following table shows the device to which we claim substantial equivalence (predicate device).

Table 18-1 Predicate Device of the OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM

Predicate Device	510(k) Number
OLYMPUS CAPSULE ENDOSCOPE SYSTEM	K090210

4 Device Description

OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM is a capsule imaging system used for visualization of the small intestine mucosa.

The OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM consists of a CAPSULE ENDOSCOPE (EC-Y0006), an ACTIVATOR (MAJ-1478), a RECORDER (RE-Y0002), a CRADLE (MAJ-Y0160), a BATTERY PACK (MAJ-Y0161), a RECORDER HOLDER (MAJ-Y0162), an ANTENNA UNIT (MAJ-Y0163), an ANTENNA HOLDER (MAJ-Y0164), an ENDOCAPSULE SOFTWARE SERVER-CLIENT (MAJ-Y0165) and an ENDOCAPSULE SOFTWARE CLIENT (MAJ-Y0166).

ENDOCAPSULE SMALL INTESTINAL CAPSULE ENDOSCOPE SET (MAJ-Y0176) is a package containing five CAPSULE ENDOSCOPEs (EC-Y0006).

ENDOCAPSULE RECORDER SET (MAJ-Y0177) is a package containing the ACTIVATOR (MAJ-1478), the RECORDER (RE-Y0002), the CRADLE (MAJ-Y0160), the BATTERY PACK (MAJ-Y0161), the RECORDER HOLDER (MAJ-Y0162), the ANTENNA UNIT (MAJ-Y0163), and the ANTENNA HOLDER (MAJ-Y0164).

The CAPSULE ENDOSCOPE (EC-Y0006) has an outer diameter of 11mm, a total length of 26mm, and is designed and manufactured with polymer composites that are biocompatible and provide sufficient tolerance to exposure to body fluids (digestive tract juice) and external compression forces. The clear top cover contains a compact objective lens in front of the image sensor. Four white light emitting diodes (LEDs) are allocated around the objective lens. The exterior casing contains operational circuits for the image sensor, LEDs, radio transmitter, and antenna for radio transmission in 315MHz. The CAPSULE ENDOSCOPE (EC-Y0006) has two silver oxide batteries to power the circuit within the capsule.

The RECORDER (RE-Y0002) is used in combination with the ANTENNA UNIT (MAJ-Y0163) for receiving signals from the CAPSULE ENDOSCOPE (EC-Y0006) and for recording image data captured by the CAPSULE ENDOSCOPE (EC-Y0006). The RECORDER (RE-Y0002) is powered by the BATTERY PACK (MAJ-Y0161). It is capable of continuously receiving and recording image data from the CAPSULE ENDOSCOPE (EC-Y0006). The RECORDER has a color LCD display panel for displaying received images, recorded images, patient ID, battery pack level, etc. The RECORDER (RE-Y0002) is inserted into a pouch on the RECORDER HOLDER (MAJ-Y0162) enabling the patient to move freely during the examination.
The BATTERY PACK (MAJ-Y0161) is charged when the RECORDER (RE-Y0002) is attached to the CRADLE (MAJ-Y0160). Unlike the predicate device that includes Battery charger (MAJ-1478), no independent battery charger is required.

The ANTENNA UNIT (MAJ-Y0163) is an integrated antenna sheet containing eight antenna elements and is stored in the ANTENNA HOLDER (MAJ-Y0164). The ANTENNA HOLDER is attached covering the patient's waist.

A workstation for observation of the image data captured by the CAPSULE ENDOSCOPE (EC-Y0006) is constructed by installing the ENDOCAPSULE SOFTWARE SERVER-CLIENT (MAJ-Y0165) or the ENDOCAPSULE SOFTWARE CLIENT (MAJ-Y0166) to a commercially available personal computer. Functions of each software are shown in the table below.

Model	Functions
ENDOCAPSULE SOFTWARE SERVER-CLIENT (MAJ-Y0165)	Observation of the image data Storage of the image data
ENDOCAPSULE SOFTWARE CLIENT (MAJ-Y0166)	Observation of the image data

When the user uses more than or equal to two workstations in the network environment, the user can select the ENDOCAPSULE SOFTWARE CLIENT (MAJ-Y0166) as the workstation from the 2nd workstation. The user can share data between two workstations or more.

The ENDOCAPSULE SOFTWARE SERVER-CLIENT (MAJ-Y0165) includes the ENDOCAPSULE SOFTWARE LIGHT which can be installed on commercially available personal computer for viewing the image data captured by the CAPSULE ENDOSCOPE (EC-Y0006). The ENDOCAPSULE SOFTWARE LIGHT is provided for user convenience.

The workstation facilitates the downloading of endoscopic image data recorded in the RECORDER (RE-Y0002) to the workstation via the CRADLE (MAJ-Y0160) for observation of patient image data. The workstation initialization function sends patient information data to the RECORDER (RE-Y0002) from the workstation via the CRADLE (MAJ-Y0160).
The workstation also provides the following functions:
- Image display whose maximum rate of the image renewal is based upon the user setting;
- Display / store images selected by the user as thumbnail data;
- Development and printing of diagnostic reports with bookmarked images;
- Image / video clip export;
- Data storage to a network server.

In addition, the image processing function offers the following user selectable functions:

- 3D Track function (new function)
  The signal reception strength of multiple antennas is calculated to estimate the capsule position, and the capsule track is displayed.
- Red Color Detection Function
  A software feature that highlights frames suspicious for blood or red lesions based upon analysis of red pixels within the image.
- Average Color Bar
  Calculates the average RGB colors of an image and displays the averaged color composite as a color line.
- Adjust mode
  Automatically adjusts the speed of frame display based upon both image movement and user setting.
- Express viewing function
  A software feature that allows for image playback and that has two playback modes. The Express-Selected mode plays back images whose mucosal area is dissimilar from that of previous image. The Express-Skipped mode plays back the images skipped in the Express-Selected mode.
- Overview function

A software feature that displays images whose mucosal area is dissimilar from that of previous images as an outline of the complete case.

5 Indications for Use

The OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM is intended for visualization of the small intestine mucosa. The Red Color Detection Function is intended to mark frames of the video suspected of containing blood or red areas.

6 Comparison of Technological Characteristics

The technological characteristics of the subject OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM are identical or similar to the predicate device identified in "3 Legally Marketed Device to which Substantial Equivalence is Claimed" above. A detailed comparison of the subject OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM with the predicate device is provided in the premarket notification.

7 Substantially Equivalent Discussion

The subject OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM is a modification to the previously cleared OLYMPUS CAPSULE ENDOSCOPE SYSTEM (K090210). The indications for use, principles of operation and fundamental technology of the subject OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM are similar or identical to the predicate device. The indicated patient population and anatomical site are also identical to the predicate device. The subject device also meets the guidance entitled "Class II Special Controls Guidance Document: Ingestible Telemetric Gastrointestinal Capsule Imaging System; Final Guidance for Industry and FDA, Document issued on: November 28, 2001." The proposed changes in this submission do not raise new safety and effectiveness issues related to device design.

Based upon the results of bench testing and clinical testing performed, we believe that the subject OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM is substantially equivalent to the identified predicate device as demonstrated by this submission.

8 Summary of non-clinical testing

The following non-clinical testing was performed.

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verifications tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

The following bench testing were performed.
1) Specification testing including "PH resistance testing", "Mechanical and structural integrity testing (including bite test)", "Battery life testing", "Field of view, depth of focus, distortion, color/illumination uniform, sensitivity of imaging sensor, color reproduction, resolution, and image noise testing", "Shock, vibration, temperature, and humidity testing", "Optical Spectrum and Phototoxicity testing (including before and after the shelf life)".
2) Side-by-side bench testing between the subject device and the predicate device including "Image quality (including displayed lines and villus, field of view, optimum working distance)" and "Antenna reception performance".
3) Evaluation of 3D track function including "Accuracy evaluation" and "Display evaluation"
4) Stability testing

The testing results showed the subject device has sufficient performance or equivalent performance to the predicate device.

The following biocompatibility testing were performed for the patient contacting parts of the EC-Y0006 and testing results met the biocompatibility requirement.
- Cytotoxicity
- Sensitization
- Acute Intracutaneous Reactivity
- Acute Oral Toxicity
- Acute Systemic Toxicity
- Implantation instead of sub-chronic toxicity

The software validation activities were performed in accordance with the FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The device software is considered a "Moderate Level of Concern."

The following standards were used during the design and validation of the subject devices:
-ISO 14971: 2007
-IEC 60601-1: 1988, Amendment 1: 1991, Amendment 2: 1995
-IEC 60601-1-1: 2000
-IEC 60601-1-2: 2001, Amendment 1: 2004
-IEC 60601-2-18: 1996, Amendment 1: 2000
-IEC 60950-1: 2005
-ISO 11135-1: 2007
-ISO 10993-1: 2009
-ISO 10993-5: 2009
-ISO 10993-6: 2007
-ISO 10993-10: 2010
-ISO 10993-11: 2006

9 Summary of clinical testing

A clinical study was performed and thirty healthy volunteers were involved in this study. The objective of the study was to evaluate the accuracy of the 3D Track function and image quality. Additionally, the performance of the new antenna was retrospectively evaluated utilizing the recorded image data in the clinical study above. The summary of the clinical study results is described below.

3D Track
The accuracy of the 3D Track function was evaluated. Healthy volunteers swallowed the capsule endoscope and underwent x-ray photography. Based upon the radiographic image data, positions of the capsule endoscope were derived. Then the positions of the capsule endoscope derived from the radiographic image and the estimated positions of the capsule endoscope at the time of the radiographic image shooting were compared. Three subjects were excluded, and therefore twenty-seven subjects were eligible. The test results met the predefined acceptance criteria. Therefore, it was verified that the accuracy of the 3D Track function was maintained as we presumed.

Image quality
Image quality of the subject device was assessed by the principal investigator questionnarie regarding resolution, brightness including evenness of illumination, color tone, and field of view. The principal investigator's comments showed that the subject device is greatly superior to the predicate device in regard to image quality.

Antenna Performance
The performance of the new antenna was evaluated since the shape and type of the antennas of the subject device is different from those of the predicate device. The evaluation was made using video gap occurrence as the indicator of the reception performance. One subject was excluded, and therefore twenty-nine subjects were eligible. The evaluation results met the predefined acceptance criteria. Thus, the reception performance of the subject device is equivalent to that of the predicate device.

10 Conclusion

When compared to the predicate device, the OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 29, 2013

OLYMPUS MEDICAL SYSTEMS CORP.
% Ms. Daphney Germain-Kolawole
Regulatory Affairs Project Manager
Olympus America, Inc.
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CENTER VALLEY PA 18034-0610

Re: K123421
Trade/Device Name: OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM
Regulation Number: 21 CFR§ 876.1300
Regulation Name: Ingestible telemetric gastrointestinal capsule imaging system
Regulatory Class: II
Product Code: NEZ
Dated: March 15, 2013
Received: March 18, 2013

Dear Ms. Germain-Kolawole:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123421

Device Name: OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM

Indications For Use:

The OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM is intended for visualization of the small intestine mucosa. The Red Color Detection Function is intended to mark frames of the video suspected of containing blood or red areas.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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